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EXAMINER
DAVIS, RUTH A

ART UNIT	PAPER NUMBER
1651	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/813,292	Applicant(s) KRINGELUM ET AL.	
	Examiner Ruth A. Davis	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-24 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-24 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1 – 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and its dependents are drawn to a method of supplying a starter culture, however are rendered vague and indefinite for reciting "with a consistent quality" because it is unclear what quality is consistent. Moreover, the claim language and/or specification fail to adequately define the "consistent quality".

The claims are further indefinite because it is unclear what steps are being performed, as they do not appear to be recited.

Claim 1 is indefinite for reciting "use of, for subsequent production of starter culture, a subset" because it is unclear how this is a step for supplying a starter culture.

Claim 1 is confusing for reciting "adjusted sufficiently in size" because it is unclear what is being adjusted and what is sufficient in size.

Claim 2 is vague and indefinite because the specification and/or claim language fail to adequately define what quantities are "sufficient" to inoculate at least 50,000 liter of cultivation medium.

Claim 3 is indefinite for reciting 10^8 CFU/g because it is unclear what the ratio is between. For example, 10^8 CFU per gram of what?

Claim 4 is rendered vague and indefinite for reciting "at a rate of maximum 0.1%" because it is unclear to what the rate refers. For example, 0.1% of what? To what does 0.1% refer?

Claim 5 is rendered vague and indefinite because it is unclear what is being claimed. The claim appears to limit the amount of inoculation material. However, it is unclear what two limitations are relative to the ratio.

Claim 7 is rendered vague and indefinite because it is unclear what the medium contains. The claim lacks a transitional phrase, thereby failing to set forth what is included or excluded from the cultivation medium.

Claim 7 is further confusing because it is unclear if the medium contains partially skim milk, partially cream, only cream, partially skimmed cream, or only skimmed cream. Moreover, it is unclear what is skimmed and what is included in and excluded from the medium.

Claim 8 and its dependent are confusing because it is unclear how the subset can be provided in liquid, frozen or dried form as it appears to be directly cultured from the stock inoculum material.

In claim 9, "the addition" lacks antecedent basis.

Claims 9 – 11 refer to an adding step in step (ii). However, this terminology is inconsistent with the recited step (ii). It is unclear if applicant is referring to a new, separate step or to the inoculation step recited in step (ii) of claim 1.

In claim 12, "provided" lacks antecedent basis. It is unclear if applicant is referring to the "supply" step (step (i)). Moreover, is the stock inoculum provided from storage in a sealed enclosure? Or is the stock inoculum provided to the cultivation medium in a sealed enclosure?

In claim 16, "the container" and "the liquid" recited in lines 2 and 4, lack antecedent basis.

In claim17, the phrase "including" renders the claim indefinite because it is unclear whether the limitation following the phrase is merely exemplary, and therefore not required, or a required feature of the claims.

Claim 20 is rendered vague and indefinite because it is unclear what is being claimed. The claim appears to limit a starter culture, however it is unclear how a starter culture can be selected from an industry. Moreover, a food industry is not a starter culture.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. Claims 1, 3, 6, 17 – 22 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Sing et al. (US 6146667).

Applicant claims a method for supplying a starter culture with a consistent quality. The method comprises

a) supplying a stock inoculum of concentrated starter cells

b) using a subset of stock inoculum to inoculate a culture medium

c) propagating starter cells to a desired amount

d) harvesting the propagated cells to produce a starter culture.

The concentrated starter cells are at least 10^8 CFU/g and after the inoculation step b), the culture medium has at least 10^5 CFU/g media. The starter cells are selected from a lactic acid bacteria, Bifidobacterium, Propionibacterium, Staphylococcus, Micrococcus, Bacillus, Enterobacteriacea, Actinomycetes, Corynebacterium, Brevibacterium, Pediococcus, Pseudomonas, Sphingomonas, Mycobacterium, Rhodococcus, a fungus, yeast, Lactococcus, Lactobacillus, Leuconostoc, Oenococcus and Streptococcus. The stock inoculum comprises at least 2 strains of starter cells and is selected from microorganisms used in the food industry, feed industry or pharmaceutical industry. The starter culture is used to inoculated milk which is processed to obtain a dairy product selected from cheese, yogurt, butter, inoculated sweet milk and liquid fermented milk. The cells propagated in step c) express a desired gene product of produce a desired product such as a pigment, flavoring compound, emulsifier, vitamin, growth stimulating compound, food additive or feed additive.

Sing et al. teaches a method of making a starter culture for inoculating milk to make a dairy product. The method comprises,

a) introducing a concentrated inoculum of at least 10^9 CFU/g to a culture medium

b) growing a subset resulting in a medium with at least 10^7 CFU/g (abstract)

c) propagating the cells to produce a starter culture with 10^9CFU/g (abstract)

d) harvesting the starter cells

and adding the starter cells to milk to produce a dairy product (abstract), such as cheese (col.1 line 45-50). Sing teaches that any known mesophilics and/or thermophilics can be used as the starter culture (or inoculum) (col.2 line 60-65) and provides examples using multiple strains of Lactococcus (col.4 line 33-38).

The reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1 – 2, 4, 11, 21 – 22 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sing et al. (US 6146667).

Applicant claims a method for supplying a starter culture with a consistent quality. The method comprises

a) supplying a stock inoculum of concentrated starter cells

b) using a subset of stock inoculum to inoculate a culture medium

c) propagating starter cells to a desired amount

d) harvesting the propagated cells to produce a starter culture.

The stock inoculum of step a) is a quantity sufficient to inoculate at least 50,000 liters of culture medium and is aseptically inoculated at a rate of 0.1%. The starter culture is used to inoculated milk which is processed to obtain a dairy product selected from cheese, yogurt, butter, inoculated sweet milk and liquid fermented milk or a pigment, flavoring compound, emulsifier, vitamin, growth stimulating compound, food additive or feed additive.

Sing et al. teaches a method of making a starter culture for inoculating milk to make a dairy product. The method comprises

a) introducing a concentrated inoculum of at least 10^9 CFU/g to a culture medium

b) growing a subset resulting in a medium with at least 10^7 CFU/g (abstract)

c) propagating the cells to produce a starter culture with 10^9CFU/g (abstract)

d) harvesting the starter cells

and adding the starter cells to milk to produce a dairy product (abstract).

Sing does not specifically teach the stock inoculum in step in amounts sufficient to inoculated 50,000 liters or that the subset is inoculated under aseptic conditions at a rate of 0.1%.

However, at the time of the invention, it would have been obvious to one of ordinary skill in the art to work under aseptic conditions because it was normal, routine practice in the art. Furthermore, it would have been obvious to one of ordinary skill in the art to optimize inoculation rate and volume because it was routine practice in the art at the time the invention was made. Moreover, at the time of the invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the claimed variables.

Sing does not teach the method wherein yogurt, butter, sweet milk, liquid fermented milk, pigments, emulsifier, vitamin, growth stimulating compound or feed additives are obtained. However, at the time of the invention, it would have been obvious to do so because it was routine practice in the art at the time the invention was made. Moreover, at the time of the invention, one of ordinary skill in the art would have been motivated by conventional practice to use the starter culture of Sing in a method to obtain the above named products because it was well known in the art.

8. Claims 1 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sing et al. in view of Czulak et al. (US 4476143).

Applicant claims a method for supplying a starter culture with a consistent quality. The method comprises

a) supplying a stock inoculum of concentrated starter cells

b) using a subset of stock inoculum to inoculate a culture medium

c) propagating starter cells to a desired amount

d) harvesting the propagated cells to produce a starter culture

wherein the culture medium comprises at least partially skim milk or cream.

Sing et al. teaches a method of making a starter culture for inoculating milk to make a dairy product. The method comprises

a) introducing a concentrated inoculum of at least 10^9 CFU/g to a culture medium

b) growing a subset resulting in a medium with at least 10^7 CFU/g (abstract)

c) propagating the cells to produce a starter culture with 10^9CFU/g (abstract)

d) harvesting the starter cells

and adding the starter cells to milk to produce a dairy product (abstract), such as cheese (col.1 line 45-50).

Sing does not teach the culture medium of step (b) comprising at least part skim milk or cream. However, Czulak et al. teaches a method of inoculating milk with a fat content of 0.3 – 1.5% (part skim and low fat milk) to produce cheese (abstract). Czulak teaches that use of skim milk enables a cheese product to be made with a substantially reduced fat content (col.1 line 10-15). At the time of the invention, one of ordinary skill in the art would have been motivated by Czulak to use a culture medium including at least part skim milk in the method of Sing with a reasonable expectation of success for obtaining a dairy product with a reduced fat content.

9. Claims 1 and 8 – 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sing et al. in view of Lizak (US 5952020).

Applicant claims a method for supplying a starter culture with a consistent quality. The method comprises

a) supplying a stock inoculum of concentrated starter cells

b) using a subset of stock inoculum to inoculate a culture medium

c) propagating starter cells to a desired amount

d) harvesting the propagated cells to produce a starter culture.

The stock inoculum and/or subset is liquid, frozen or dried, is thawed before inoculating into the culture medium and the subset is combined with an aqueous medium to obtain a suspensions of cells before inoculating the culture medium.

Sing et al. teaches a method of making a starter culture for inoculating milk to make a dairy product. The method comprises

a) introducing a concentrated inoculum of at least 10^9 CFU/g to a culture medium

b) growing a subset resulting in a medium with at least 10^7 CFU/g (abstract)

c) propagating the cells to produce a starter culture with 10^9CFU/g (abstract)

d) harvesting the starter cells

and adding the starter cells to milk to produce a dairy product (abstract).

Sing does not teach the stock inoculum and/or subset wherein it is liquid, frozen or dried wherein a frozen inoculum is thawed and a dried subset is combined with an aqueous medium before inoculating into the culture medium. However, it would have been obvious to do so because it was conventional practice in the art at the time of the invention. In support, Lizak teaches conventional storage of starting cultures includes liquid culture, frozen culture and dried culture (col.6 line 53-59). Although Lizak does not specifically teach frozen cultures are thawed and dried cultures are suspended in a liquid medium before inoculation, it was well known in the art to do so at the time of the invention. Therefore, at the time of the invention, one of ordinary skill in the art would have been motivated by conventional practice to obtain stock inoculum

and/or subset cultures as a liquid, frozen or dried, thaw it and/or suspend the dried culture in a liquid medium because it was routine in the art as demonstrated by Lizak.

10. Claims 1 and 12 – 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sing et al. in view of Vandenbergh et al. (US 6068774) and Matsumiya et al. (US 5225346).

Applicant claims a method for supplying a starter culture with a consistent quality. The method comprises

a) supplying a stock inoculum of concentrated starter cells

b) using a subset of stock inoculum to inoculate a culture medium

c) propagating starter cells to a desired amount

d) harvesting the propagated cells to produce a starter culture.

The stock is provided in a sealed enclosure made from a flexible material selected from polyolefin, substituted olefin, copolymer of ethylene, polypropylene, polyethylene, polyester, polycarbonate, polyamide, acrylonitrile, a cellulose derivative or metal foil. The enclosure has a cubic content of at least 0.01 l (10ml) and an outlet for connecting to the culture medium container, which allows for aseptic inoculation.

Sing et al. teaches a method of making a starter culture for inoculating milk to make a dairy product. The method comprises

a) introducing a concentrated inoculum of at least 10^9 CFU/g to a culture medium

b) growing a subset resulting in a medium with at least 10^7 CFU/g (abstract)

c) propagating the cells to produce a starter culture with 10^9CFU/g (abstract)

d) harvesting the starter cells

and adding the starter cells to milk to produce a dairy product (abstract).

Sing does not teach that the stock inoculum is provided in a sealed enclosure made from a flexible material selected from polyolefin, substituted olefin, copolymer of ethylene, polypropylene, polyethylene, polyester, polycarbonate, polyamide, acrylonitrile, a cellulose derivative or metal foil with a cubic content of at least 0.01 l (10ml) wherein the sealed enclosure has an outlet for connecting to the culture medium container, which allows for aseptic inoculation. However, Vandenbergh et al. teaches starter cultures can be stored in leak-proof containers such as a plastic bag, plastic container, metal foil, or sealable containers (col.4 line 30-40). While Vandengergh does not teach the material used or size of such contaniers, Matsumiya et al. discloses cell culture containers made from ethylene copolymers, polyethylene, polypropylene, acrylonitrile copolymers (col.1 line 30-37). In addition, Matsumiya teaches that the flexible, bag like structures have an inlet tube and an outlet tube with a coupler at its end (col.1 line 23-30). At the time of the invention, one of ordinary skill in the art would have been motivated to provide a stock inoculum in a sealed enclosure because it was well known in the art to do so as demonstrated by Vandengergh. Furthermore, it would have been obvious to one of ordinary skill in the art to optimize the capacity of such containers to correspond with volume of the culture because it was routine practice in the art at the time of the invention.

11. Claims 1 and 17 – 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sing et al. in view of Czulak and Lizak.

Applicant claims a method for supplying a starter culture with a consistent quality. The method comprises

a) supplying a stock inoculum of concentrated starter cells

b) using a subset of stock inoculum to inoculate a culture medium

c) propagating starter cells to a desired amount

d) harvesting the propagated cells to produce a starter culture.

The starter cells are selected from a lactic acid bacteria, Bifidobacterium, Propionibacterium, Staphylococcus, Micrococcus, Bacillus, Enterobacteriacea, Actinomycetes, Corynebacterium, Brevibacterium, Pediococcus, Pseudomonas, Sphingomonas, Mycobacterium, Rhodococcus, a fungus, yeast, Lactococcus, Lactobacillus, Leuconostoc, Oenococcus and Streptococcus.

Sing et al. teaches a method of making a starter culture for inoculating milk to make a dairy product. The method comprises

a) introducing a concentrated inoculum of at least 10^9 CFU/g to a culture medium

b) growing a subset resulting in a medium with at least 10^7 CFU/g (abstract)

c) propagating the cells to produce a starter culture with 10^9CFU/g (abstract)

d) harvesting the starter cells

and adding the starter cells to milk to produce a dairy product (abstract), such as cheese (col.1 line 45-50). Sing teaches that any known mesophilics and/or thermophilics can be used as the starter culture (or inoculum) (col.2 line 60-65) and provides examples using multiple strains of Lactococcus (col.4 line 33-38).

Sing does not teach the method using starter cells from Bifidobacterium, Propionibacterium, Staphylococcus, Micrococcus, Bacillus, Enterobacteriacea, Actinomycetes, Corynebacterium, Brevibacterium, Pediococcus, Pseudomonas, Sphingomonas, Mycobacterium, Rhodococcus, a fungus, yeast Lactobacillus, Leuconostoc, Oenococcus and Streptococcus.

However, at the time of the invention, each of the above organisms were well known and used in the art as sources of starter cultures. In support, Czulak et al. teaches a method of inoculating milk with Lactobacillus and Streptococcus cultures whereby the cultures produce a desired cheese flavor (abstract). In further support, Lizak teaches starter cultures of fungus, Bacillus, combinations thereof and yeasts genetically altered to express enzymes (col.6 line 10-21). Therefore, at the time of the invention, one of ordinary skill in the art would have been motivated by routine practice to use the above named microorganisms in the method of Sing with a reasonable expectation of successfully obtaining a starter culture.

12. Claims 1, 20 and 22 – 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sing et al. in view of Rimler et al. (US 980523) and Lizak.

Applicant claims a method for supplying a starter culture with a consistent quality. The method comprises

a) supplying a stock inoculum of concentrated starter cells

b) using a subset of stock inoculum to inoculate a culture medium

c) propagating starter cells to a desired amount

d) harvesting the propagated cells to produce a starter culture.

The starter cells are selected from microorganisms used in the food industry, feed industry or pharmaceutical industry and are used to inoculated milk which is processed to obtain a dairy product selected from cheese, yogurt, butter, inoculated sweet milk and liquid fermented milk. Alternatively, the cells propagated in step c) express a desired gene product of produce a desired product such as an enzyme, pharmaceutically active substance, polysaccharide or amino acid

Sing et al. teaches a method of making a starter culture for inoculating milk to make a dairy product. The method comprises

a) introducing a concentrated inoculum of at least 10^9 CFU/g to a culture medium

b) growing a subset resulting in a medium with at least 10^7 CFU/g (abstract)

c) propagating the cells to produce a starter culture with 10^9CFU/g (abstract)

d) harvesting the starter cells

and adding the starter cells to milk to produce a dairy product (abstract), such as cheese (col.1 line 45-50).

Sing does not teach the method wherein the starter cells are use in the pharmaceutical industry and express a desired gene product such as an enzyme, pharmaceutically active substance, polysaccharide or amino acid. However, at the time of the invention, it would have been obvious to one of ordinary skill in the art to do so because it was a well known practice in the art at the time the invention was made. In support, Rimler et al. teaches a method of propagating starter cells of Haemophilus in order to obtain products useful as immunological agents (abstract). Stock cultures of the bacteria are passed twice (or propagated, sub-cultured and propagated), cultured in a medium, inoculated into a starter culture tube and propagated (col.3 line 1-15) to obtain the desired pharmaceutically active substance. In further support, Lizak teaches starter cultures of fungus, Bacillus, combinations thereof and yeasts genetically altered to express enzymes (col.6 line 10-21). Moreover, at the time of the invention, one of ordinary skill in the art would have been motivated by conventional practice to obtain a desired gene product via the methods of Sing.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 703-308-6310. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ruth A. Davis; rad
December 7, 2001

LEON B. LANKFORD, JR.
PRIMARY EXAMINER